DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

MAY 19 2004

Our STN: BL 103948/5036

ILEX Pharmaceuticals L.P.
Attention: Michael Bernstein, MPH
Senior Director, Regulatory Affairs
4545 Horizon Hill Boulevard
San Antonio, TX 78229

Dear Mr. Bernstein:

Your request to supplement your biologics license application for Alemtuzumab received on November 20, 2003, to revise the Human Pharmacokinetics subsection of the Clinical Pharmacology section of the package insert has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see http://www.fda.gov/cder/biologics/default.htm. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

This information will be included in your biologics license application file.

Sincerely,

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Patricia Keegan, M.D.
Director
Division of Therapeutic Biological Oncology Products
Office of Drug Evaluation VI
Office of New Drugs
Center for Drug Evaluation and Research

Enclosures: Package insert

CONCURRENCE PAGE

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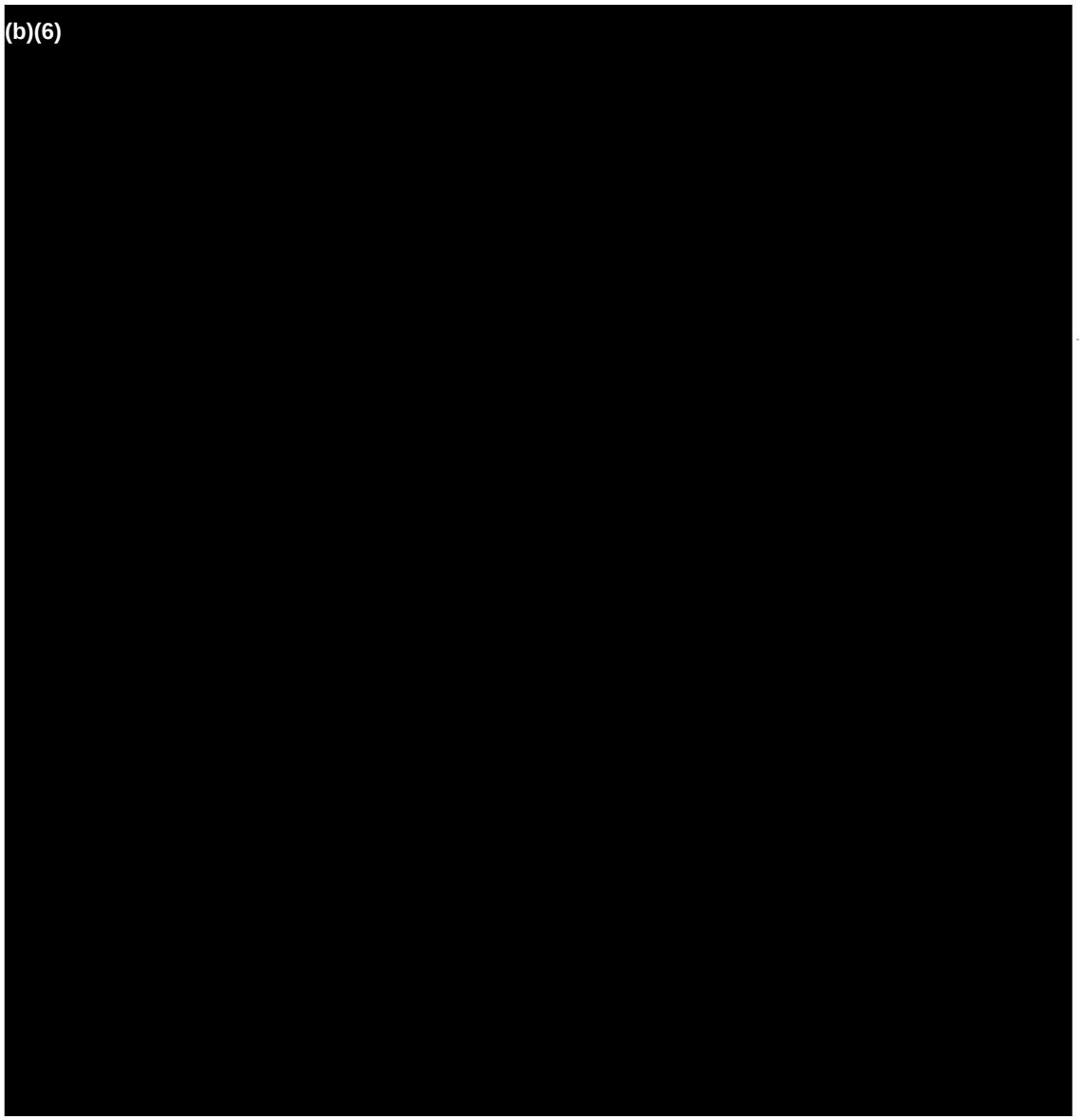

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